PCN36

THE ESTIMATED IMPACT OF IN VITRO BIOMARKERS ON THE COST-EFFECTIVENESS OF POPULATION-WIDE COLORECTAL CANCER SCREENING

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OBJECTIVES: Most screening options for colorectal cancer (CRC) are invasive and patient compliance in population wide screening programs is low. Recently, potential candidates for blood-based biomarker tests for early cancer detection have been described. Here we perform an extensive cost-effectiveness analysis of integrated diagnostic screening workflows to determine the anticipated impact of incorporating two candidate in vitro biomarkers, CCSA-3 immunoassay and SEPT9 epigenetics testing, on both patient mortality and medical costs. **METHODS:** Markov Cycle Tree models were constructed to simulate disease progression and screening for 4 million people, representative of the U.S. population, aging from 50 to 80. Eight workflows were constructed from combinations of Optical Colonoscopy (OC), CT Colonography (CTC), Fecal Occult Blood Test (FOBT), Immunoassay (CCSA-3), and Epigenetics (SEPT9). Kernel density estimation was performed on raw biomarker data to generate disease-state probability distributions of biomarker levels for sensitivity and specificity calculations. Finally, we perform sensitivity analysis on the sensitivity and specificity of a generic in vitro diagnostic test. **RESULTS:** CRC screening workflows that include initial screening with inexpensive in vitro diagnostic tests given every 3 years outperform others in both cost and effectiveness. Incremental costs compared with No Screening are as follows: OC $1.4B increase, SEPT9 $582M increase, CCSA-3 $2.8B decrease. Life-years saved: OC 78,535, SEPT9 185,839, CCSA-3 216,434. Despite having lower sensitivity and specificity, the low-cost and minimally-invasive nature of these tests allow more frequent screening, resulting in better detection of early stage disease than with OC alone. **CONCLUSIONS:** Though currently there are no blood-based biomarkers approved for early colorectal cancer screening, we can assess the expected impact of these tests once developed on colorectal cancer in the U.S. population. A complete sensitivity analysis of the sensitivity and specificity of a hypothetical biomarker provides a map of cost-effectiveness within which any test developed will fall.

PCN37

AN ECONOMIC EVALUATION OF CIRCULATING TUMOR CELLS DETECTION IN METASTATIC BREAST CANCER

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OBJECTIVES: Metastatic breast cancer (MBC) is a costly and burdensome disease in the United States. In 2008, an estimated 182,460 women will receive a new diagnosis of breast cancer and 40,480 will die from the disease. The objective of this study was to conduct a cost-effectiveness analysis of a diagnostic test for circulating tumor cells (CTC) (CellSearch®) plus imaging versus imaging alone. **METHODS:** This study used a probabilistic Markov cost-utility analysis based on a pivotal clinical trial evaluating the CellSearch® technology. The perspective of the study was that of a managed care organization. The primary basis for estimates of transitions between health states were derived from the pivotal trial evaluating CellSearch®. Using patient level data, transition probabilities were developed for patients with CTC counts of < 5 or ≥ 5 over 3 month intervals. The same approach was used for imaging studies where imaging was classified as either regression or stable disease or progressive disease. Utility estimates were obtained from the literature. The model took into account estrogen/progesterone receptor status as well as HER2 receptor status. Costs were based on Medicare fee schedules or those reported in the literature. **RESULTS:** The mean number of Quality Adjusted Life Years (QALYs) for imaging was 13.60 (SD = 1.88) as compared to 15.32 (SD = 1.44) for CellSearch® plus imaging ($p > 0.05$). The annualized treatment and monitoring costs of using CellSearch® plus imaging was higher than imaging alone ($56,392 vs. $44,408, $p > 0.05$). Cost-effectiveness acceptability curves indicated that CellSearch® plus imaging had a higher probability of being cost-effective than imaging alone when willingness to pay per QALY exceeded $7,500. **CONCLUSIONS:** This analysis suggests that CellSearch® combined with imaging may be a cost-effective strategy for monitoring patients with MBC. The additional cost of the technology relative to the additional gains in QALYs falls well below commonly cited thresholds for accepting new technologies.

PCN38

COST-EFFECTIVENES ANALYSIS OF DOCETAXEL VERSUS STANDARD REGIMEN AS THE INDUCTION CHEMOTHERAPY OF LOCALLY ADVANCED HEAD AND NECK SQUAMOUS CELL CARCINOMA IN POLAND

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OBJECTIVES: To conduct a cost effectiveness analysis (CEA) of docetaxel plus cisplastin and 5-fluorouracil (TPF) vs cisplastin and 5-fluorouracil (PF) as induction chemotherapy followed by concurrent chemoradiation (RCT TAX 324) or radiation therapy (RCT TAX 323) in locally advanced unresectable head and neck squamous cell carcinoma (HNSCC) in Poland. **METHODS:** We constructed two cost-effectiveness Markov models (basing on TAX 324 or TAX 323) which include four health states: stable, response, progression and death. The CEA was conducted from both payers' perspective (National Health Fund and patient), using clinical data from published sources, Polish cost data and a 15-year time horizon and annual discount rate of costs and benefits at 5%. **RESULTS:** Based on a systematic review two randomized clinical trials were included in the comparison TAX 323 and TAX 324. Average costs of the treatment for HNSCC (including chemotherapy, radiation or chemoradiation therapy, treatment of serious adverse events, surgery, health state monitoring, relapse treatment and palliative care) were: PLN54,708 for TPF and PLN40,614 for PF basing on TAX 324 and PLN46,107 for TPF and PLN27,510 for PF basing on TAX 323. Basing on TAX 324 treatment effects (per patient) were 4.3631 LYG vs. 3.4183 LYG respectively for TPF and PF regimens. Basing on TAX 323 treatment effects (per patient) were 1.9694 LYG for TPF vs. 1.6875 LYG for PF. ICER for the TPF vs. PF comparison for trial TAX 324 was PLN14,916.40/LYG and PLN65,958.51/LYG for trial TAX 323. **CONCLUSIONS:** The docetaxel regimen is more effective and more expensive in the induction treatment of patients with locally advanced unresectable HNSCC compared with PF chemotherapy. ICERs are below the acceptable threshold, therefore the docetaxel therapy can be considered a cost-effective treatment for locally advanced unresectable HNSCC in Poland.

PCN39

COST-EFFECTIVENESS ANALYSIS OF LUNG CANCER SCREENING WITH COMPUTED TOMOGRAPHY

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OBJECTIVES: Given a high cost again high incidence of lung cancer lung cancer screening with Computed Tomography (CT) is a debatable issue within medical community. **METHODS:** We performed a health economic analysis via computer simulation to track the annual transition among five health states (disease free, preclinical disease, local disease with treatment, advanced lung cancer, and death) with a probabilistic Markov model. The primary scenario mimics that of the Dutch-Belgian randomised lung cancer multi-slice CT screening trial (NELSON) study. The primary endpoint was the incremental cost- effectiveness and cost-utility (quality-adjusted life year, QALY) ratio (ICER and ICUR). Model parameters were derived from literatures. Model validation on stage-specific case finding, survival rate, and treatment related cost were simulated and compared with literatures. **RESULTS:** Model validation revealed comparable results between estimation and observation. In our primary scenario, the mean ICER was 51,774 USD/LY. If 50,000 USD/LY was taken as the threshold of willingness to pay, there was 48% or so chance that CT screening will be cost-effective. When quality-of-life related health utility was taken into consideration, the mean ICUR was 730,966 (USD/QALY). When other screening schedules were simulated and compared, intensive screening (such as annual screening) is no cost-effective. **CONCLUSIONS:** Our simulation reveals that population-based lung cancer screening with CT is not cost -effective. This result provides an evidence for policy-makers on lung cancer screening before the results of randomized controlled studies available.

PCN40

A COST-EFFECTIVENESS ANALYSIS OF BENDAMUSTINE AT A TERTIARY CANCER CENTER

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OBJECTIVES: This study evaluates the cost-effectiveness and budget impact of bendamustine, a recently approved alkylating mechlorethamine derivative for the treatment of chronic lymphocytic leukemia (CLL), as part of the Formulary Management System at a major tertiary cancer center in the United States. **METHODS:** Decision analytical models were developed to estimate the cost-effectiveness of bendamustine in CLL patients receiving either first-line or salvage therapy. The first-line model compared bendamustine alone versus a combination therapy of fludarabine, cyclophosphamide, and rituximab (FCR). The salvage model also compared bendamustine alone to the same FCR combination for CLL therapy. The outcome of interest was progression-free life years (PFLY), based on published literature and clinical use estimates. Direct institutional medical costs for a one-year time period were utilized. In addition, a budget impact analysis was also conducted for adding bendamustine to the Formulary. **RESULTS:** Bendamustine is more convenient – only a single infusion is required compared to multiple infusions for the FCR combination. However, based on outcome estimates from literature and the application of the institutional costs, bendamustine was found to be less costly and also less effective. The cost per PFLY saved by using the FCR combination for treatment of CLL for first-line therapy was $2964. The cost was $5553 per PFLY saved for the same FCR combination for the treatment of CLL in salvage therapy. The budget impact model showed that the institution will utilize about $6.43 million worth of bendamustine annually based on acquisition costs and estimated usage. **CONCLUSIONS:** Bendamustine appears to be less cost-effective than other therapeutic regimens for the treatment of CLL. Bendamustine was added to the Formulary as a second- or third-line option for both model indications. Future economic analyses will be conducted to determine how closely the current economic model predicts actual utilization and cost-effectiveness at the institution.

PCN41

EVIDENCE SYNTHESIS FOR MODELING THE NATURAL HISTORY OF ANAL PENILE AND OROPAHRYNGEAL CANCERS

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OBJECTIVES: Substantial evidence on the increased incidence of HPV-associated malignancies is mounting as a result of on-going natural history studies on HPV infections as well as vaccination trials. Yet, there remains a paucity of results from